

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

PLASTIC SURGERY ASSOCIATES, S.C., a Wisconsin corporation, INFINITY SPA ORLANDO, LLC, a Florida corporation, GREEN CHRYSALIS ENTERPRISE, LLC d/b/a THE FACE PLACE, a Texas corporation, RENEW SKIN & LASER CENTERS, LLC d/b/a DERMACARE OF HAMPTON ROADS, a Virginia corporation, ARIZONA ADVANCED AESTHETICS, PLLC d/b/a ENHANCED IMAGE MED SPA, an Arizona corporation, ADVANCED HEALTH WEIGHT LOSS, S.C. d/b/a OPTIONS MEDICAL WEIGHT LOSS, an Illinois corporation, *on behalf of themselves and all others similarly situated,*

Plaintiffs,

Case No. 17-cv-11850

v.

CYNOSURE, INC.,

Defendant.

**DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' CLASS ACTION COMPLAINT**

NOW COMES Defendant, CYNOSURE, INC., by and through its attorneys, SMITHAMUNDSEN LLC, and for its answer to Plaintiffs' Class Action Complaint, Defendant states:

**I. NATURE OF THE CASE**

1. In 2015, Cynosure, Inc. began selling the SculpSure Non-Invasive Body Contouring Platform ("SculpSure") to physicians, aesthetic surgery practices, and medical spas (or "med spas") in the United States. Cynosure marketed SculpSure as an effective way for the medical practices to reduce fat in a patient's midsection through the use of laser technology.

**ANSWER:** Cynosure admits only that during and after 2015, it marketed and sold the SculpSure, and that its customers included physicians, aesthetic surgery practices, and medical spas in the United States. Cynosure denies the remaining allegations as stated in Paragraph 1 of Plaintiffs' Class Action Complaint.

2. As part of an aggressive campaign to induce Plaintiffs and the Class to purchase the almost \$200,000 machine, Cynosure made several uniform material misrepresentations regarding the key attributes of the SculpSure device. Cynosure uniformly claimed that: (a) only one, simple 25-minute treatment achieved 24% fat loss; (b) SculpSure is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) the procedure could be performed "hands free" without a physician or trained staff member needing to be present during the majority of the treatment.

**ANSWER:** Cynosure denies the allegations as stated in Paragraph 2 of Plaintiffs' Class Action Complaint.

3. Yet Cynosure's representations have proven false. SculpSure seldom achieves results in patients after *multiple* treatments—much less so with just the single procedure Cynosure claimed would suffice. And to even have a chance at achieving results, operators must turn the power level so high that it causes intolerable pain for the patient, necessitating that the operator remain in the room to monitor patient comfort. In some cases, the operator must stop the procedure altogether.

**ANSWER:** Cynosure denies the allegations as stated in Paragraph 3 of Plaintiffs' Class Action Complaint.

4. Practices across the country have thus found SculpSure detrimental to their business.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 4 of Plaintiffs' Class Action Complaint.**

5. By recommending it, practitioners risk good will, encouraging patients to pay thousands for a procedure they do not believe in themselves. A practice cannot be expected to push SculpSure to clients when the company that built the machine routinely fails to advise how to achieve results, how many treatments to perform, and how much pain patients should expect.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 5 of Plaintiffs' Class Action Complaint.**

6. Performing the treatment also threatens to drain resources while taxing doctors and staff members. As the unsuccessful treatments add up, offices must futilely work with Cynosure to find a solution, deal with complaints from unsatisfied patients, and perform retreatments or alternative procedures.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 6 of Plaintiffs' Class Action Complaint.**

7. Finally, continue to own the machine jeopardizes the practices' financial health. The device's failures render it incapable of recouping its significant cost—a number that continues to grow with each refund or free retreatment necessarily offered to keep customers happy.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 7 of Plaintiffs' Class Action Complaint.**

8. In short, Cynosure has marketed to physicians, aesthetic surgery facilities, and med spas a costly device that has proved unusable in those very practices.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 8 of Plaintiffs' Class Action Complaint.**

9. SculpSure is thus effectively useless for the purpose for which it was intended. The device cannot be used in the way that Cynosure marketed it. Nor can it be used in an otherwise commercially viable manner.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 9 of Plaintiffs' Class Action Complaint.**

10. Plaintiffs and the Class have been in fact deceived by Cynosure's representations, did not receive the benefit of the bargain, and suffered actual damages.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 10 of Plaintiffs' Class Action Complaint.**

## **II. PARTIES**

11. Plastic Surgery Associates, S.C. is a Wisconsin service corporation operating at N4W22370 Bluemound Rd, Waukesha, WI 53186. Plastic Surgery Associates provides cosmetic treatments, plastic surgery, and skin care to its patients, and bought a SculpSure in December 2015. Its purchase agreement with Cynosure refers to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Plastic Surgery Associates] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston.” Plastic Surgery Associates was injured in its property and business by the actions of Defendant as described herein.

**ANSWER: Cynosure admits only that Plastic Surgery Associates, S.C. purchased a SculpSure from Cynosure, pursuant to a purchase agreement. The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms**

**of the agreement. Cynosure denies that Plastic Surgery Associates, S.C. was injured in its property and business by the actions of Cynosure as described herein or otherwise. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 11 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

12. Infinity Spa Orlando, LLC operates at 25 West Kaley Street in Orlando, Florida. Infinity Spa Orlando specializes in facial and body contouring procedures. In June 2016, it acquired a SculpSure from Defendant pursuant to a purchase agreement subject to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Infinity Spa Orlando] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Infinity Spa Orlando was injured in its property and business by the actions of Defendant as described herein.

**ANSWER: Cynosure admits only that Infinity Spa Orlando, LLC purchased a SculpSure from Cynosure in June 2016, pursuant to a purchase agreement. The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms of the agreement. Cynosure denies that Infinity Spa Orlando, LLC was injured in its property and business by the actions of Cynosure as described herein or otherwise. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 12 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

13. Green Chrysalis Enterprise, LLC is a Texas limited liability company doing business as The Face Place at 104 Grapevine Hwy, Suite 200, Hurst, TX 76054. The Face Place

offers various facial, cosmetic, and aesthetic medical treatments to its patients. It purchased SculpSure from Defendant in February 2016. The purchase agreement with Cynosure refers to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [The Face Place] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” The Face Place was injured in its property and business by the actions of Defendant as described herein.

**ANSWER:** **Cynosure admits only that Green Chrysalis Enterprise, LLC purchased a SculpSure from Cynosure in February 2016, pursuant to a purchase agreement. The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms of the agreement.**  
**Cynosure denies that Green Chrysalis Enterprise, LLC was injured in its property and business by the actions of Cynosure as described herein or otherwise.**  
**Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 13 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

14. Renew Skin & Laser Centers, LLC is a Virginia limited liability company doing business as Dermacare of Hampton Roads (“Dermacare”) at 747 Volvo Parkway in Chesapeake, Virginia. Dermacare operates as a med spa offering various cosmetic and aesthetic medical treatments to its patients. Dermacare purchased SculpSure from Defendant on December 15, 2015. That purchase agreement refers to terms and conditions that provide “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts.

[Dermacare] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Dermacare was injured in its property and business by the actions of Defendant as described herein.

**ANSWER:** Cynosure admits only that Renew Skin & Laser Centers, LLC purchased a SculpSure from Cynosure, pursuant to a purchase agreement. The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms of the agreement. Cynosure denies that Renew Skin & Laser Centers, LLC was injured in its property and business by the actions of Cynosure as described herein or otherwise. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 14 of Plaintiffs’ Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.

15. Arizona Advanced Aesthetics, PLLC is an Arizona professional limited liability company doing business as Enhanced Image Med Spa at 7942 W. Bell Rd., Glendale, AZ 85308. Enhanced Image Med Spa specializes in facial and body contouring procedures. In early 2016, Enhanced Image Med Spa acquired a SculpSure from Defendant pursuant to a purchase agreement subject to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Enhanced Image Med Spa] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Enhanced Image Med Spa was injured in its property and business by the actions of Defendant as described herein.

**ANSWER:** Cynosure admits only that Arizona Advanced Aesthetics, PLLC purchased a SculpSure from Cynosure in 2016, pursuant to a purchase agreement.

**The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms of the agreement.**

**Cynosure denies that Arizona Advanced Aesthetics, PLLC was injured in its property and business by the actions of Cynosure as described herein or otherwise. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 15 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

16. Advanced Health Weight Loss, S.C. is a service corporation operating as Options Medical Weight Loss at 1147 S Wabash Ave. in Chicago, Illinois. It purchased a SculpSure in 2016. Its purchase agreement with Cynosure refers to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Options Medical Weight Loss] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Options Medical Weight Loss was injured in its property and business by the actions of Defendant as described herein

**ANSWER: Cynosure admits only that Advanced Health Weight Loss, S.C. purchased a SculpSure from Cynosure in 2016, pursuant to a purchase agreement. The purchase agreement speaks for itself, and allegations contained in this paragraph seeking to characterize same are denied to the extent they mischaracterize or are otherwise inconsistent with the terms of the agreement. Cynosure denies that Advanced Health Weight Loss, S.C. was injured in its property and business by the actions of Cynosure as described herein or otherwise. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 16 of Plaintiffs' Class Action**

**Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

17. Defendant Cynosure is a corporation incorporated and existing under the laws of Delaware with its principal place of business located at 5 W Carlisle Road, Westford, Massachusetts, 01886. Defendant Cynosure has developed and marketed several medical devices and lasers, including SculpSure, which it has sold to medical practitioners internationally.

**ANSWER: Cynosure admits that it is a corporation incorporated and existing under the laws of Delaware with its principal place of business located at 5 Carlisle Road, Westford, Massachusetts, 01886. Cynosure further admits that it has developed and marketed several medical devices and lasers, including SculpSure, which it has sold to medical practitioners internationally.**

### **III. JURISDICTION AND VENUE**

18. This Court has jurisdiction and venue is proper because the action arises from acts and occurrences within the Commonwealth of Massachusetts, the Defendant Cynosure is headquartered in Westford, Massachusetts, and the parties agreed, via a choice-of-law provision and forum selection clause in their purchase agreements, to submit all disputes to a court in Boston, Massachusetts subject to Massachusetts law.

**ANSWER: Cynosure admits only that this Court has jurisdiction, that venue is proper, that Cynosure maintains its headquarters in Westford, Massachusetts, and that the purchase agreements entered into by Cynosure and each plaintiff contain a choice-of-law provision and forum selection clause indicating that all disputes under the agreement shall be submitted to a court in Boston, Massachusetts, and subject to**

**Massachusetts Law. Cynosure denies the remaining allegations as stated in**

**Paragraph 18 of Plaintiffs' Class Action Complaint.**

#### **IV. FACTUAL BACKGROUND**

##### **A. The noninvasive body-contouring market is a lucrative place for medical device manufacturers to compete**

19. Noninvasive body-contouring procedures constitute a large and rapidly growing sector of the cosmetic surgery market in the United States, with the number of operations performed having increased by approximately 6% in 2016 compared to the previous year.<sup>1</sup>

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 19 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

20. These procedures aim to eliminate stubborn fat from certain areas of the body. Body-contouring, however, differs from liposuction. Liposuction uses suction techniques to surgically extract fat deposits from specific areas of the body. Because liposuction requires anesthesia, it is typically an outpatient procedure at a surgery center, or if large amounts of fat are being removed, the procedure will be done in a hospital and may require an overnight stay. Patients typically return to work after several days and to normal activities within two weeks.<sup>2</sup>

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<sup>1</sup> The American Society for Aesthetic Plastic Surgery, "2016 Cosmetic Surgery National Data Bank Statistics," at 12, available at <http://www.surgery.org/sites/default/files/ASAPS-Stats2016.pdf>.

<sup>2</sup> *Liposuction*, MAYO CLINIC (Nov. 29, 2016), <http://www.mayoclinic.org/tests-procedures/liposuction/home/ovc-20197272>; *How to Choose Between Liposuction and Noninvasive Fat Reduction Procedures*, AM. BD. OF COSMETIC SURGERY BLOG (Aug. 19, 2015), <http://www.americanboardcosmeticsurgery.org/liposuction/how-to-choose-between-liposuction-and-noninvasive-fat-reduction-procedures/>; *Liposuction*, MEDINCENET, <http://vvvvv.medicinenet.com/liposuction/page3.htm> (last visited September 21, 2017).

**ANSWER: Cynosure admits only that some noninvasive body-contouring procedures are performed for the purpose of eliminating stubborn fat from certain areas of the body. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 20 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

21. Body-contouring, by contrast, uses noninvasive medical devices (*e.g.*, lasers) to eliminate or shrink fat cells without an incision or anesthesia. Practitioners most commonly (and most effectively) employ it to diminish small pockets of stubborn fat and reduce the circumference of a patient's midsection and flanks. These procedures are commonly performed in a physician's office or med spa without anesthesia and are appealing because they do not require any recovery time.<sup>3</sup>

**ANSWER: Cynosure admits only that some body-contouring procedures involve the use of noninvasive medical devices to eliminate or shrink fat cells without an incision or anesthesia, and that some such procedures may be performed in a physician's office or med spa without anesthesia. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 21 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

22. Body-contouring devices began appearing on the market approximately 10 years ago, and several companies have developed different technologies to achieve the desired results.<sup>4</sup>

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<sup>3</sup> AM. BD. OF COSMETIC SURGERY BLOG *supra* note 2; Deborah Kotz, *CoolSculpting and Zerona: Body Sculpting Without Surgery*, US NEWS & WORLD REPORT (Sept. 17, 2010, 1:26 p.m), <http://health.usnews.com/health-news/blogs/on-women/2010/09/17/coolsculpting-and-zerona-body-sculpting-without-surgery>.

<sup>4</sup> Am. BD. OF COSMETIC SURGERY BLOG, *supra* note 2.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 22 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

23. For example, Zerona uses a low-level laser to target superficial fat cells. The laser does not destroy or kill the fat cells, but disrupts their membranes causing them to release their contents. The end result is that the affected fat cells shrink, causing a reduction in the belly, waist, or body size of the patient. Patients feel no pain. However, because the treatment only targets superficial fat cells, it typically takes about six to twelve 40-minute treatments to achieve results.<sup>5</sup>

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 23 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

24. Another technology, CoolSculpting, uses a process called cryolipolysis to kill fat cells. Because fat cells freeze at higher temperatures than the surrounding tissue, the CoolSculpting device can deliver cold temperatures through the skin to freeze fat cells without damaging the skin. Targeted fat cells eventually die before the body removes them through its natural processes, yielding a reduction in size in the treated area. However, because the machine works by pulling a patient's skin into the device to apply very cold temperatures, patients frequently experience discomfort for the first five to 10 minutes of the procedure.

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<sup>5</sup> *How Does the Zerona Laser Work?*, MYZERONA.COM, <http://www.myzerona.com/what-is-zerona.html> (last visited May 8, 2017); R. Stephen Mulholland, Malcolm D. Paul, & Charbel Chalfoun, *Noninvasive Body Contouring with Radiofrequency, Ultrasound Cryolysis, and Low-Level Laser Therapy*, 38 CLINIC IN PLASTIC SURGERY 503, 514-17 (2011), available at [http://www.invasix.com/upload/articles/peerrev\\_clips\\_titeamention.pdf](http://www.invasix.com/upload/articles/peerrev_clips_titeamention.pdf); Kotz, *supra* note 3.

The entire procedure takes about an hour, but unlike the Zerona procedure, CoolSculpting can often take only one visit to achieve results.<sup>6</sup>

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 24 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**B. Cynosure develops SculpSure to compete against other body-contouring machines**

25. Cynosure, located in Westford, Massachusetts, is a corporation that specializes in the marketing and sale of medical devices utilizing laser technology for cosmetic and aesthetic use. Specifically in the area of noninvasive body-contouring, Cynosure sells a device it calls "SculpSure."<sup>7</sup>

**ANSWER: Cynosure admits that it is a corporation with headquarters located in Westford, Massachusetts, and that it markets and sells medical devices utilizing laser technology for cosmetic and aesethetic use, including a device called "SculpSure" that is marketed for use in noninvasive body-contouring procedures.**

26. Cynosure developed and manufactured SculpSure from its Westford offices to compete in the noninvasive body-contouring market against Zerona, CoolSculpting, and similar devices. The machine uses a laser to heat adipose tissue (loose connective tissue in which fat cells accumulate<sup>8</sup>) to a temperature between 42°C and 47°C. Cynosure claimed this would cause the targeted fat cells to eventually die before being removed by the body's lymphatic system.<sup>9</sup>

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<sup>6</sup> *How It Works*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/how-it-works/> (last visited May 9, 2017); *What To Expect*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/what-to-expect/> (last visited May 9, 2017); *FAQs*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/faqs/> (last visited May 9, 2017); Kotz, *supra* note 3;

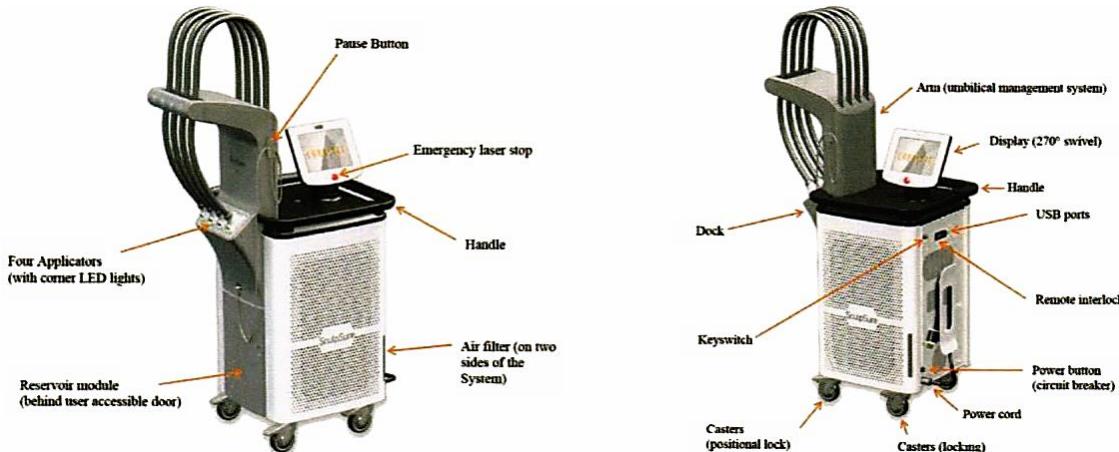
<sup>7</sup> *About Cynosure*, CYNOSURE, <http://www.cynosure.com/about-cynosure/> (last visited May 9, 2010); *SculpSure*, CYNOSURE, <http://www.cynosure.com/product/sculpsure/> (last visited May 9, 2010).

<sup>8</sup> *Adipose Tissue*, DICTIONARY.COM, <http://www.dictionary.com/browse/adipose-tissue>.

<sup>9</sup> *SculpSure*, CYNOSURE, <http://www.cynosure.com/product/sculpsure/> (last visited May 9, 2010).

**ANSWER:** Cynosure admits only that it developed SculpSure in Westford, that the SculpSure can heat adipose tissue to a temperature between 42°C and 47°C when used properly, and that Cynosure has represented that such heating would cause some of the targeting fat cells to die and eventually be removed by the body's lymphatic system. Cynosure denies the remaining allegations as stated in Paragraph 26 of Plaintiffs' Class Action Complaint.

27. The machine has four long, flexible arms that are part of what Cynosure calls the "umbilical management system." At the end of each arm is a rectangular applicator.<sup>10</sup> Sample pictures follow:



**ANSWER: Admit.**

28. During the procedure, the operator arranged several plastic frames onto the patient's body in the treatment area, applies a lotion to certain areas of the patient's skin within those frames, and then attaches the rectangular applicators to those frames.<sup>11</sup>

<sup>10</sup> SculpSure Operator's Manual (Rev. 4, Apr. 2016), at 12.

<sup>11</sup> SculpSure Clinical Reference Guide (Rev. 2), at 24-28.



**ANSWER: Cynosure admits only that it recommends for an operator of a SculpSure machine to arrange plastic frames onto the patient's body in the desired treatment area, apply a lotion to certain areas of the patient's skin, and attach rectangular applicators to the frames. Cynosure denies the remaining allegations as stated in Paragraph 28 of Plaintiffs' Class Action Complaint.**

29. Each applicator used during the procedure consumes one "PAC." PAC's are credits that Cynosure loads onto a PAC Key. Without a sufficiently loaded PAC Key inserted into the USB port on the SculpSure, the machine will not function. Med spas and physicians must therefore purchase PAC Keys from Cynosure in advance before treating patients. As of April 2016, a PAC Key came loaded with 100 PAC's and cost \$5,000.<sup>12</sup>

**ANSWER: Cynosure admits only that each applicator used during a SculpSure procedure consumes one "PAC." Cynosure denies the remaining allegations as stated in Paragraph 29 of Plaintiffs' Class Action Complaint.**

30. Once the applicators are in place, the operator initiates treatment. Treatment has two phases: "build mode" and "sustain mode." Build mode occurs for the first four minutes of the procedure, during which the machine attempts to "heat[] the fat to the target temperature."

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<sup>12</sup> SculpSure Operator's Manual (Rev. 4, Apr. 2016), at 36; CYNO - Q1 2016 Cynosure Inc Earnings Call, at 3 (Apr. 26, 2016).

Sustain mode lasts the remaining 21 minutes and aims to “maintain[] the target temperature in the fat layer.”<sup>13</sup>

**ANSWER: Cynosure admits only that it recommends for an operator of a SculpSure machine to initiate treatment after applicators are in place, and that treatment occurs in a four-minute “build” phase during which fat is heated to the target temperature plus a 21-minute “sustain” phase during which the target temperature of the fat is sustained. Cynosure denies the remaining allegations as stated in Paragraph 30 of Plaintiffs’ Class Action Complaint.**

31. The machine can deliver energy in a range of 0.90 to 1.40 Watts per square centimeter ( $\text{W}/\text{cm}^2$ ), in increments of  $0.05 \text{ W}/\text{cm}^2$ . The build mode power density setting defaults to  $1.10 \text{ W}/\text{cm}^2$ .



**ANSWER: Admit.**

32. Despite the default setting being set to  $1.10 \text{ W}/\text{cm}^2$ , SculpSure directs that the operator start at a low level and increase the power, adjusting the heat based on patient feedback. Initially, Cynosure released the following Zone Adjustment Chart to guide the treatment:<sup>14</sup>

<sup>13</sup> SculpSure Clinical Reference Guide (Rev. 2), at 29.

<sup>14</sup> SculpSure Clinical Reference Guide (Rev. 2), at 32.

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. No change in setting.
4	Longer peaks of moderate deep warmth and cooling. No change in setting.
	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

Fat Destruction Zone



**ANSWER:** Cynosure admits only that it recommends for the operator of a SculpSure machine to start treatment at a low power level and increase the power based on patient feedback. Cynosure further admits that it published the Zone Adjustment Chart depicted herein. Cynosure denies the remaining allegations as stated in Paragraph 32 of Plaintiffs' Class Action Complaint.

33. When the patient reports "moderate deep warmth and cooling periods, the operator should maintain that level.<sup>15</sup>

**ANSWER:** Cynosure denies the allegations as stated in Paragraph 33 of Plaintiffs' Class Action Complaint.

34. According to Cynosure, at this point, the operator can leave the patient in the room with a "transmitter button to page [the staff]" in the event he or she patient experiences heat or discomfort beyond "moderate deep warmth and cooling." The operator can then return to provide an "Advance-to-Cool" shot for temporary relief to the patient.<sup>16</sup>

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<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 31-32

**ANSWER: Cynosure denies the allegations as stated in Paragraph 34 of Plaintiffs' Class Action Complaint.**

35. At no time during marketing of SculpSure did Cynosure report that patients would feel pain, have to endure heat to the point of an intense burning sensation, or require any painkiller or anesthesia.

**ANSWER: Cynosure admits only that it did not represent in its marketing of SculpSure that patients would require any painkiller or anesthesia during procedures. Cynosure denies the remaining allegations as stated in Paragraph 35 of Plaintiffs' Class Action Complaint.**

**C. Cynosure aggressively markets SculpSure to physicians and practitioners as a superior device requiring only one 25-minute, pain-free treatment to achieve results**

36. The FDA cleared Cynosure to market its SculpSure device in mid-2015. Cynosure in turn planned to officially launch the product later that year.<sup>17</sup>

**ANSWER: Admit.**

37. By autumn 2015, Cynosure was engaged in a motivated campaign to sell SculpSure to various cosmetic surgery providers, med spas, and practitioners across the country. From its Massachusetts headquarters, the company developed a consistent, uniform message to distinguish SculpSure from its competitors (namely CoolSculpting). Cynosure created videos (both for the practitioners to which it marketed and for use with the practices' prospective clients), brochures, webpages, presentations, and other promotional materials reflecting that consistent

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<sup>17</sup> *FDA Clears Expanded Use for Cynosure Lipolysis Device*, MEDICAL PRODUCT OUTSOURCING (Jul. 7, 2015), [http://www.mpo-mag.com/contents/view\\_breaking-news/2015-07-07/fda-clears-expanded-use-for-cynosure-lipolysis-device/](http://www.mpo-mag.com/contents/view_breaking-news/2015-07-07/fda-clears-expanded-use-for-cynosure-lipolysis-device/).

message.<sup>18</sup> Cynosure distributed these materials to potential purchasers through its website, marketing department, and sales representatives.

**ANSWER: Cynosure admits that it marketed and sold SculpSure during autumn 2015 and that its customers included cosmetic surgery providers, med spas, and other practitioners. Cynosure further admits that it created promotional materials for SculpSure, some of which were distributed to potential purchasers. Cynosure denies the remaining allegations as stated in Paragraph 37 of Plaintiffs' Class Action Complaint.**

38. Specifically, Cynosure emphasized three aspects of the device critical to purchasers.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 38 of Plaintiffs' Class Action Complaint.**

39. First, Cynosure uniformly represented to potential buyers that patients would achieve “[d]efined success,” “[m]aximal performance,” or “optimal results” in one, 25-minute treatment. According to Cynosure’s website and marketing brochures, just one treatment would eliminate up to 24% body fat in the treated area.<sup>19</sup> Before and after photos showed marked results from just “a single treatment in one anatomical area.” And by purportedly achieving these end results in only 25 minutes, Cynosure had a straightforward way to distinguish its product from CoolSculpting<sup>20</sup>:

**ANSWER: Cynosure admits only that SculpSure’s 25-minute treatment session time distinguishes it from CoolSculpting and that before-and-after photos have shown successful results from a single SculpSure treatment in one anatomical area. Cynosure**

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<sup>18</sup> See Cynosure Investor Event (Presentation) (Sep. 15, 2015).

<sup>19</sup> SculpSure, [CYNOSURE.COM, https://www.cynosure.com/product/sculpsure/](https://www.cynosure.com/product/sculpsure/) (last visited Aug. 17, 2017); SculpSure Product Presentation (Nov. 2015), at 8.

<sup>20</sup> SculpSure Product Presentation (Nov. 2015), at 7, 12-44.

**denies the remaining allegations as stated in Paragraph 39 of Plaintiffs' Class Action Complaint.**

40. This efficiency was particularly attractive to potential buyers. If the procedure truly took 25 minutes, those who owned a SculpSure could perform more treatments in a day without having to tax their staff, hire more employees, or perform follow-up with the patient. Furthermore, the minimal time commitment provided practices with a key marketing tool to convince patients to opt for the procedure, especially when compared to SculpSure's existing competitors.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 40 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

41. Second, Cynosure stressed that the procedure would be a comfortable and pain-free experience for patients, despite the fact that SculpSure utilized very high temperatures to eliminate the fat cells.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 41 of Plaintiffs' Class Action Complaint.**

42. According to Cynosure, SculpSure's "Contact Cooling" system would "assist in maintaining safe and comfortable skin surface temperatures." At the proper setting, Cynosure claimed that SculpSure would cause no more than "long[] peaks of moderate deep warmth and cooling."<sup>21</sup> Cynosure's marketing brochures assured that "[m]ost patients feel a tingling sensation intermittently which is well tolerated"<sup>22</sup> and "[c]omfortable."<sup>23</sup> To demonstrate the tolerability of the procedure, Cynosure marketing videos showed women

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<sup>21</sup> SculpSure Clinical Reference Guide (Rev. 2), at 9, 32.

<sup>22</sup> SculpSure Marketing Brochure (2015), at 2.

<sup>23</sup> SculpSure Product Presentation (Nov. 2015), at 8.

casually using cell phones, tablets, or e-readers during the procedure without any visible signs of discomfort and without any staff present in the room to monitor them.<sup>24</sup> Consistent with these representations, Cynosure also held live demonstrations at various promotional events where a model would sit and supposedly receive the treatment while talking to audience members to illustrate how painless the procedure was.

**ANSWER: Cynosure admits only that SculpSure’s “Contact Cooling” system assists the operator of a SculpSure device to maintain a patient’s skin surface temperature at a safe level and that Cynosure published marketing materials state that “[m]ost patients feel a tingling sensation intermittently which is well tolerated.” Cynosure denies the remaining allegations as stated in Paragraph 42 of Plaintiffs’ Class Action Complaint.**

43. To compare, CoolSculpting’s suction mechanism and intense cold meant patients would have to endure a few minutes of discomfort during the procedure. So SculpSure offered the promise of attracting those patients who may be more hesitant to body contouring.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 43 of Plaintiffs’ Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

44. Third, Cynosure promoted the device as “hands-free,”<sup>25</sup> including a pager system with the device that would allow staff to “leav[e] the treatment room” but still communicate with patients. In its manual, Cynosure noted that a patient could use the transmitter to request “a magazine or water” during the treatment even though the staff member may not be in the room.<sup>26</sup>

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<sup>24</sup> See, e.g., DocWeb, *SculpSure – Head to Head Treatment*, YOUTUBE (Jan. 16, 2016) <https://www.youtube.com/watch?v=Def18hMKfzI> (last visited Sep. 5, 2017).

<sup>25</sup> Cynosure Investor Event (Presentation) (Sep. 15, 2015).

<sup>26</sup> SculpSure Operator’s Manual (Rev. 4, Apr. 2016), at 35.

And in online promotional videos, Cynosure showed patients being left alone in the treatment room after only a few minutes.<sup>27</sup>

**ANSWER: Cynosure denies the allegations as stated in Paragraph 41 of Plaintiffs' Class Action Complaint.**

45. If staff could leave the room, the could utilize their time more efficiently, assisting other patients, taking care of paperwork, or even performing a separate procedure. Potential purchasers naturally found this potential aspect of the device appealing.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 45 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

46. All told, Cynosure's efforts to sell the machine promoting these supposed qualities were successful.<sup>28</sup> Cynosure has sold hundreds of SculpSure devices since 2015 and 2016, with approximately 350 in the vicinities of five cities (Boston, Los Angeles, Miami, Chicago, and New York City) alone.<sup>29</sup>

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<sup>27</sup> DocWeb, *SculpSure – Head to Head Treatment*, YOUTUBE (Jan. 16, 2016), <https://www.youtube.com/watch?v=Def18hMKFzI> (last visited Sep. 5, 2017).

<sup>28</sup> See CYNO - Q1 2016 Cynosure Inc Earnings Call, at 3 (Apr. 26, 2016) ("By virtually every measure SculpSure continues to exceed our expectation."); CYNO — Q2 2016 Cynosure Inc Earnings Call, at 3 (Jul. 26, 2016) ("Revenue for the quarter increased to a record \$110.3 million, 32% higher than the year-over-year period. The primary contributors to the top-line results were SculpSure, our exciting new hyperthermic laser treatment for noninvasive fat reduction . . ."); CYNO — Q3 2016 Cynosure Inc Earnings Call, at 3 (Oct. 25, 2016) ("I will now update you on SculpSure, which has generated meaningful revenue for the past four full quarters and continues to outperform our expectations."); CYNO — Q4 2016 Cynosure Inc Earnings Call, at 3 (Feb. 07, 2017) ("SculpSure, one full year into its launch, remains ahead of our expectations. Q4 set the high watermark for SculpSure placements in a single quarter.").

<sup>29</sup> See *Patients*, CYNOSURE, <http://patients.cynosure.com/> (searching for SculpSure machines located within 100 miles of the following zip codes: 02201, 90001, 33018, 60611, and 10018).

**ANSWER: Cynosure admits only that it sold approximately 67 SculpSure devices to customers with locations in Boston, Los Angeles, Miami, Chicago, or New York City between the beginning of 2015 and the end of 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 46 of plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

47. Hologic, Inc., who acquired Defendant for approximately \$1.44 billion in early 2017, consistently singled out SculpSure when discussing reasons for the massive acquisition of the company.<sup>30</sup>

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 47 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**D. SculpSure does not work as represented, rendering the product effectively useless for practitioners and physicians**

48. Nevertheless, Cynosure's representations about SculpSure proved to be false. In short, Cynosure misrepresented SculpSure's capability as a simple, one-and-done treatment without pain.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 48 of Plaintiffs' Class Action Complaint.**

49. From the onset, patients failed to achieve results from SculpSure despite being treated as directed using Cynosure's Zone Adjustment Chart. Cynosure subsequently revised its treatment protocol for SculpSure. In April 2016, Cynosure introduced a "Treat to Complete" treatment plan, advising doctors to manage a patient's "expectations that multiple

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<sup>30</sup> HOLX — Hologic Inc to Acquire Cynosure Inc Conference Call, at 4, 6-7, 9 (2017)

treatments may be part of the treatment plan.”<sup>31</sup> Yet the “Treat to Complete” protocol directly contradicted Cynosure’s marketing of SculpSure as a one-time, 25-minute treatment—with the latter message still advertised today on Cynosure’s website.<sup>32</sup>

**ANSWER: Cynosure admits only that the SculpSure Clinical Reference Guide it published in April 2016 included a “Treat to Complete” treatment plan for the SculpSure in April 2016 and suggested that practitioners manage a patient’s expectations that multiple treatments may be part of the treatment plan.” Cynosure denies the remaining allegations as stated in Paragraph 49 of Plaintiffs’ Class Action Complaint.**

50. Furthermore, Cynosure directed physicians and practitioners to raise the power levels on the machine to compensate for the poor results, contradicting prior claims that any setting between 0.9 and 1.4 W/cm<sup>2</sup> would suffice. Cynosure even suggested that once patients appear to have reached the threshold level they can tolerate, the operator should then “bump” the setting higher without the patient’s knowledge.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 50 of Plaintiffs’ Class Action Complaint.**

51. But even at lower power levels, many experienced significant pain. Practitioners reported that patients would jump off the treatment table, howl in agony, or even demand the operator stop the machine because they could not tolerate the procedure. Such circumstances paint a far different picture than the so-called “tingling sensation[s]” that Cynosure claims are “well-tolerated.”<sup>33</sup>

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<sup>31</sup> SculpSure Clinical Reference Guide (Rev. 4, Apr. 2016), at 15.

<sup>32</sup> SculpSure, [CYNOSURE.COM, https://www.cynosure.com/product/sculpsure/](https://www.cynosure.com/product/sculpsure/) (last visited Sep. 5, 2017) (claiming that a “single treatment” provided “[d]efined success” with an “[a]verage reduction in fat volume” of “[u]p to 24%.”).

<sup>33</sup> SculpSure Marketing Brochure (2015), at 2.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 51 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

52. The patient experience also makes it impossible for the operator to leave the treatment room and renders the pager system on the device useless. In practice, the procedure requires practitioners to stay in the room for the entire 25 minutes, and thus Cynosure's promise of a "hand-free" treatment is untrue. Operators constantly need to adjust the device's levels, provide "Advance to Cool" shots, or coach patients through the pain.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 52 of Plaintiffs' Class Action Complaint.**

53. Nor can practices simply administer anesthesia to make the procedure more bearable. The treatment requires feedback from patients to determine the appropriate energy level. If patients lack the ability to feel any pain or excessive heat in the treated area, then they cannot provide the necessary response to the doctor to lower the power level on the machine. Moreover, administering anesthesia would render the procedure inappropriate for med spas or other medical offices—the very practices for whom SculpSure was designed and to which it was marketed. And anesthesia, or even a strong oral analgesic, would require time before the procedure to administer it, downtime after the treatment to allow the patient to recover, and a doctor to monitor the patient to make sure he or she was fit to leave, any of which would render the promise of a 25-minute procedure false.

**ANSWER: Cynosure admits only that use of anesthesia during a SculpSure treatment session is not advised and that proper procedure for using the SculpSure requires patient feedback. Cynosure denies the remaining allegations as stated in Paragraph 53 of Plaintiffs' Class Action Complaint.**

54. Given patients' experiences with the treatment, Cynosure had to update its Zone Score Adjustment Chart on multiple occasions. Initially Cynosure claimed that a power level correlating with “[t]ingly, short intervals of warmth and cooling” in the patient would result in “fat destruction.” Yet by April 2016, it removed that claim. This time it maintained that results would require “[p]rickling, pinching, pressure, [and] longer peaks of moderate deep heat and cooling”<sup>34</sup>—an artful, yet still erroneous description of the distress many patients experienced. Not to mention, the description completely contradicts the one still advertised by Cynosure on its website: a “comfortable,” “gentle, warming sensation” that “fl[ies] right by.”<sup>35</sup>

Rev. 2 (2015)

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. No change in setting.
4	Longer peaks of moderate deep warmth and cooling. No change in setting.
Fat Destruction Zone	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

Rev. 4 (April 2016)

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. Increase setting.
4	Longer peaks of moderate deep warmth and cooling. No change in setting.
Fat Destruction Zone	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

Rev. 7 (August 2016)

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. Increase setting.
4	Prickling, pinching, pressure, longer peaks of moderate deep heat and cooling. No change in setting.
Fat Destruction Zone	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

<sup>34</sup> Compare SculpSure Clinical Reference Guide (Rev. 2), with SculpSure Clinical Reference Guide (Rev. 4, Apr. 2016), and SculpSure Clinical Reference Guide (Rev. 7, Nov. 2016)

<sup>35</sup> SculpSure, [CYNOSURE.COM, https://www.cynosure.com/product/sculpsure/](https://www.cynosure.com/product/sculpsure/) (last visited Aug. 17, 2017) (claiming that a “single treatment” provided “[d]efined success” with an “[a]verage reduction in fat volume” of “[u]p to 24%.”)

**ANSWER: Cynosure admits that revisions to the Clinical Reference Guide it publishes for use with the SculpSure machine have included updates to the “Zone Score Adjustment Chart” contained therein. Cynosure denies the remaining allegations as alleged in Paragraph 54 of Plaintiffs’ Class Action Complaint.**

55. Ultimately, the situation has left practices in an impossible position. They have spent hundreds of thousands of dollars on a machine that does not work as Cynosure represented. At the same time, they lack the ability to recoup that cost; practices cannot continue to recommend a cosmetic procedure to their patients knowing that it is likely to involve several painful treatments, but unlikely to be effective.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 55 of Plaintiffs’ Class Action Complaint.**

**E. Plaintiffs experiences with SculpSure demonstrate how Cynosure uniformly misrepresented SculpSure’s attributes and how the device remains unfit for its intended purpose**

**1. Plastic Surgery Associates cannot achieve results with SculpSure, leaving it with a useless device**

56. Plastic Surgery Associates provides cosmetic treatments, plastic surgery, and skin care to patients from its facilities in Waukesha, Wisconsin. The practice is operated by Dr. Christopher Hussussian, and Dr. Thomas Korkos.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 56 of Plaintiff’s Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

57. In mid-October 2015, Dr. Hussussian attended an American Society of Plastic Surgeons (ASPS) meeting in Boston, Massachusetts, where he first learned of SculpSure.

Cynosure representatives presented the meeting goers with videos and marketing materials reflecting its uniform misrepresentations and describing SculpSure as cutting edge versus its competitors. The presentation claimed that SculpSure offered a significantly better patient experience compared to Coolsculpting while achieving the same end result. Specifically, Cynosure promised a reduction in fat of approximately 24% in less time than Coolsculpting, but with much less discomfort. In fact, the Cynosure booth contained a model who demonstrated SculpSure's advertised comfort level by talking to eventgoers while supposedly receiving an actual treatment.

**ANSWER: Cynosure admits only that its representatives were present at an American Society of Plastic Surgeons (ASPS) meeting in Boston, Massachusetts in October 2015, and that they presented attendees with videos and other information about the SculpSure. Cynosure denies that it presented any uniform misrepresentations about SculpSure. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 57 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

58. Dr. Hussussian expressed interest in SculpSure at the event. So around November 2015 Cynosure sent a sales representative to visit the offices of Plastic Surgery Associates. The representative stressed several points, each consistent with the videos, presentations, and marketing materials produced by Cynosure to that point. She noted that SculpSure only required a one-time, 25-minute treatment, and was practically painless for patients such that it would not require any anesthesia or analgesic. Further, the device was so easy to operate, that the operator could leave the room after only a few minutes and need not be present to adjust treatment levels throughout.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 58 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

59. Given Cynosure's representations in their presentations, marketing materials, and meetings, Drs. Hussussian and Korkos opted to make the purchase.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

60. In January 2016, Plastic Surgery Associates took delivery of the machine. Shortly thereafter, Krista Stoll from Cynosure came to its facilities to train the staff. During training, Ms. Stoll again reiterated what had been told to Plastic Surgery Associates to that point, both in marketing presentations and by the sales representative. Stoll stressed that one treatment should suffice to obtain results. She advised to adjust the levels on the machine based on patient comfort; any level within the range of 0.9 and 1.4 W/cm<sup>2</sup> could achieve optimal results. Plastic Surgery Associates then began treating patients according to the clinical reference guide, operator's manual, and in-person training.

**ANSWER: Cynosure admits only that it shipped the SculpSure to Plastic Surgery Associates on December 23, 2015, and that Krista Stoll went to the Plastic Surgery Associates office to provide an initial SculpSure clinical training on January 22, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 60 of Plaintiff's**

**Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

61. By April 2016, Plastic Surgery Associates' patients had not seen any results. So Plastic Surgery Associates reached out to Cynosure who sent Ms. Stoll on May 24, 2016 to conduct a second training. At this second training, Cynosure introduced new straps and advised the staff of the "Treat to Complete" protocol. Ms. Stoll explained that a patient would now need more PACs applied to the treatment area and at least two treatments, which contradicted the original promise of a one-time procedure. Ms. Stoll also suggested that to achieve better results, the operator should "push" the settings higher.

**ANSWER: Cynosure admits only that Krista Stoll went to the Plastic Surgery Associates office to provide a follow-up SculpSure clinical training on May 24, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 61 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

62. Over the next several months, results with the machine did not improve. So on September 9, 2016, Plastic Surgery Associates held another meeting with Cynosure. At the meeting, Cynosure Practice Support Partners Maria Zucchero and Kasey Lawrence emphasized operators would need to increase the levels and provide patients with multiple treatments. Ms. Zucchero offered complementary PAC Keys to treat initial patients a second time. Following the meeting, Plastic Surgery Associates began contacting and retreating approximately 30 patients.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 62 of Plaintiffs' Class Action**

**Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

63. Two months later, Cynosure held a third training session at Plastic Surgery Associates, per the request of Tina Bock, a Cynosure Advanced Clinical Partner. Ms. Bock reiterated that the operator would need to “push” the settings higher during treatment to at least 1.1 or 1.2 W/cm<sup>2</sup> to get results. To accomplish this, she suggested that once the operator finds the appropriate level that patients can tolerate, the operator should then increase the settings without their knowledge. If the patient notices and cannot tolerate the higher level, the operator can then taper it back down.

**ANSWER: Cynosure admits only that Tina Bock, a Cynosure Advanced Clinical Partner, provided following up clinical training to Plastic Surgery Associates on November 10, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 63 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

64. But following Cynosure’s direction proved no more successful, and just caused further issues. By “pushing” the levels, patients often screamed in pain. Some screams echoed throughout the facilities, disturbing other patients and staff while creating an unsettling atmosphere throughout the office. Many patients simply could not tolerate the pain and demanded it be stopped. And someone had to be in the treatment room at all times to monitor the patient and treatment levels, proving the promise of a “hands-free” treatment from Cynosure’s marketing false.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 64 of Plaintiff's Class Action**

**Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

65. In June 2017, Plastic Surgery Associates requested a refund for the device.

Cynosure's Regional Sales Director for the Midwest took the position it could not offer a refund because the practice also owned a CoolSculpting device, and has since ceased responding to Plastic Surgery Associates regarding SculpSure.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 65 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

66. Since the June 2017 meeting, Plastic Surgery Associates has pulled its marketing for the device. It has also stopped recommending the procedure, directing patients toward CoolSculpting instead, with which it has obtained significantly better results. The staff has completely lost faith both in SculpSure's effectiveness, as well as Cynosure's willingness to do anything about the problems with the device.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 66 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**2. Infinity Spa cannot in good faith recommend SculpSure to its clients after patients consistently report excessive pain but fail to achieve positive results even after several treatments**

67. Infinity Spa Orlando is a boutique med spa located in Orlando, Florida, and managed by Lisa Christensen, M.D., Sharon Gallardy, A.R.N.P., and Diane Orlando, A.R.N.P.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 67 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

68. In December 2015, Ms. Gallardy and Ms. Orlando attended a conference at the Loews Portofino Bay Hotel in Orlando, Florida held by Cynosure. There, doctors and representatives from Cynosure presented its new device, SculpSure. Using PowerPoint presentations and promotional videos, speakers described the science and technology and praised certain aspects of the treatment and experience. In particular, the presenters highlighted SculpSure's: (1) results—save a few exceptions, patients saw a 20-24% decrease in fat after just one treatment; (2) treatment experience—the treatment lasted just 25 minutes and the operator could leave the room; and (3) tolerability—patients reported little to no pain. Videos played for the audience showing patients smiling during the procedure and experiencing no discomfort while the operator left the room. And Cynosure even gave a live demonstration of the treatment, where a Cynosure employee supposedly received the treatment without showing any signs of distress.

**ANSWER: Cynosure admits only that Cynosure presented information about SculpSure at a conference in Orlando, Florida in December 2015. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 68 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

69. Cynosure's presentations at the conference impressed Gallardy and Orlando, who then discussed purchasing the device with Christensen. In early 2016, the three contacted Cynosure.

Cynosure sent them emails, repeating the claims above, and included links to marketing materials, videos, and presentations that similarly promoted the results, treatment experience, and tolerability of the procedure. Consistent with those materials, Cynosure's sales representative aggressively hyped the machine in writing, reiterating the same points. The representative stated that "in 25 min with no discomfort . . . SculpSure will destroy 25% of a person's fat." He further noted the operator could leave during the procedure, telling Infinity Spa to "KEEP IN MIND THE PROCEDURE IS UNATTENDED SO ONCE YOU HOOK THEM UP AND START THE LASER YOU CAN DO OTHER THINGS." The "bottom line," according to the representative, was that SculpSure took only "25 minutes," "melt[ed] 25% of a patient[']s fat during 1 treatment," and would be "painless."

**ANSWER: Cynosure admits only that Cynosure provided information to Infinity Spa Orlando regarding the SculpSure. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 70 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

71. In June 2016, via a financing agreement with Ascentium Capital, Infinity Spa purchased a SculpSure for \$165,123.75 based on these representations.

**ANSWER: Cynosure admits only that Infinity Spa Orlando purchased a SculpSure for \$165,123.75 in June 2016 pursuant to an agreement with Ascentium Capital, LLC. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 71 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

72. Training occurred shortly thereafter with Lindsay Webber from Cynosure. As part of training, Webber treated Christensen, Gallardy, and Orlando. Ms. Orlando immediately realized the treatment's capacity for serious pain, describing it as similar to experiencing labor contractions without any pain medication. Gallardy also found the experience uncomfortable, and not at all in tune with the descriptions provided by Cynosure up until that point. Not one of them achieved results at any point.

**ANSWER: Cynosure admits only that Lindsay Webber provided Infinity Spa Orlando with an initial clinical training on SculpSure on June 28, 2016 and that Lisa Christensen, Sharon Gallary, Shannon Orlando and Diane Orlando were treated as part of this training. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 72 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

73. Infinity Spa treated a few patients over the summer and fall, none of whom fared better. The treatment caused pain and patients reported a lack of results. Infinity Spa in turn reported its dissatisfaction to Cynosure. So in November 2016, Cynosure contacted Infinity Spa to "check up" on the practice and arrange a second training, this time with Mary Bots. But the second training proved no more encouraging.

**ANSWER: Cynosure admits only that Mary Bots conducted a follow-up visit and clinical training on SculpSure at Infinity Spa Orlando on November 1, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 73 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

74. At the second training, Bots oversaw Dr. Christensen treat Gallardy, who found the procedure so painful she experienced presyncope (the state of lightheadedness, nausea, and blurred vision that precedes fainting, but without losing consciousness). The pain even carried over into the following days, when the treated area became red, swollen, and inflamed.

**ANSWER: Cynosure admits only that Mary Bots oversaw treatment of Gallardy.**

**Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 74 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

75. About a month later, in December 2016, Infinity Spa asked to meet with Cynosure representatives before a conference being held in Orlando. While seemingly reluctant, Cynosure eventually acquiesced, and the parties met for approximately an hour before the conference to discuss Infinity Spa's lack of results. Cynosure proposed that Infinity Spa offer to retreat its patients twice more for a total of three treatments, claiming for the first time that multiple treatments may be needed to see results. Cynosure said that it would reimburse Infinity Spa for the money spent on PAC's for these retreatments. Infinity Spa agreed and retreated all of its prior patients for a second and third time. None achieved results.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 75 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

76. SculpSure has left Infinity Spa in a predicament. The machine cost the business a significant amount of money. But given their own dreadful experiences with the procedure and their clients' universal dissatisfaction, the staff has found it impossible to recommend SculpSure in

good faith. The business thus lacks the ability to recoup the expense, to say nothing of the time and good will lost trying in vain to make it work.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations as stated in Paragraph 76 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

77. In March 2017, Infinity Spa asked Cynosure to take back the laser for a refund. Cynosure refused. Lacking any other viable option, Infinity Spa informed Ascentium Capital that it could repossess the device.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 77 of Plaintiffs' Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**3. The Face Place attempts to make SculpSure work for over a year to the detriment of its practice**

78. The Face Place operates in the Dallas-Fort Worth area of Texas, and provides various cosmetic procedures to its clients. The Face Place is run by its Practice Manager and owner, Donna Green.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 78 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

79. In February 2016, Ms. Green had been contemplating the purchase of a CoolSculpting device for her practice so she placed a call to a CoolSculpting sales

representative. While she waited to hear back, Lance Baird of Cynosure approached her. Baird wanted to promote SculpSure, which he declared would “put Coolsculpting out of business.” According to Baird, a single 25-minute procedure, achieved results “equal to” or “better” than CoolSculpting but “with less discomfort.” He described the procedure as very tolerable, with no medications or anesthetics needed. And he boasted that that Cynosure has “actually had tons of coolsculpt customers (some with multiple units) purchasing SculpSure for their practices because faster and less pain is what every patient wants, and more profitable is what very business owner wants.”

**ANSWER: Cynosure admits only that Lance Baird provided Ms. Green with information regarding SculpSure. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 75 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

80. Baird followed up by providing Green with Cynosure’s marketing materials, all of which proved consistent with Baird’s sales pitch. One video claimed a single 25-minute treatment would destroy up to 24% of subcutaneous fat.<sup>36</sup> Another video portrayed a practitioner treating two patients in the time it took CoolSculpting to treat one while leaving the treatment room for both.<sup>37</sup> And an online article stated “most patients feeling nothing more than a deep warming sensation.”<sup>38</sup>

**ANSWER: Cynosure admits only that Lance Baird provided Ms. Green with information regarding SculpSure. Cynosure has insufficient knowledge to form a**

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<sup>36</sup> Face RX Md, *How SculpSure™ Works* (Nov. 8, 2015), <https://www.youtube.com/watch?v=vhdwEFURh9Y> (last visited Aug. 15, 2017).

<sup>37</sup> Medical Spa Lasers, *SculpSure- The Ice Age is Over* (Oct. 21, 2015), <https://www.youtube.com/watch?v=6vn0gPSKSU> (last visited Sep. 6, 2017).

<sup>38</sup> Sheryl Kraft, *A New Way to Get Rid of Unwanted Fat*, MYSOCALLEDMIDLIFE, (Feb. 15, 2016), <http://sherylkraft.com/a-new-way-to-get-rid-of-unwanted-fat/>.

**belief as to the truth or falsity of the remaining allegations as stated in Paragraph 80 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

81. On February 29, 2016, Baird came to The Face Place to meet with Ms. Green. Baird once again made claims consistent with the marketing materials regarding SculpSure being a painless, one-time treatment with results comparable or better to CoolSculpting. Green, relying on these representations, agreed to buy the device and the next day began working with Heartland Business Credit to finance the \$167,250.00 purchase price.

**ANSWER: Cynosure admits only that The Face Pace purchased a SculpSure on February 29, 2016 for \$165,750.00 Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 81 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

82. Cynosure delivered the device in early March 2016, with training occurring shortly thereafter. Melissa Williams and Sonja McDonnell attended from Cynosure. During training, Williams and McDonnell repeated the same claims from Cynosure's marketing efforts. They told Ms. Green and her staff that the device was the "easiest laser" they would ever operate. The procedure was so simple and painless, they claimed, that the operator could leave the room after a few minutes to perform a Botox treatment on another client while SculpSure finished the job. But these claims would be immediately contradicted by the ensuing events.

**ANSWER: Cynosure admits only it shipped a SculpSure to The Face Place on March 3, 2016, and that an initial clinical training on the SculpSure was provided on March 22, 2016. Cynosure has insufficient knowledge to form a belief as to the**

**truth or falsity of the remaining allegations as stated in Paragraph 82 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

83. As part of training, the two Cynosure representatives performed SculpSure on Ms. Green and her staff. But the level of pain she witnessed did not at all resemble what had been promised. One staff member described it as feeling like her "skin was going to come off." Green's own treatment was agonizing. And all six who received the treatment reported at the very least extreme discomfort.

**ANSWER: Cynosure admits only that as part of clinical training, Melissa Williams oversaw treatments using the SculpSure. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations as stated in Paragraph 83 of Plaintiff's Class Action Complaint, and therefore neither admits nor denies such allegations but demands strict proof thereof.**

84. Williams and McDonnell acted surprised by the staff's inability to tolerate the pain, and assured them that the procedure would be indeed quite tolerable for patients and the situation was simply a unique case.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 84 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

85. Following training, The Face Place began taking patients. Yet these people fared no better. Patients repeatedly complained about the pain of the procedure, with several claiming they would never go through it again nor recommend it to others.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 85 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

86. In June 2017, Dupree emailed to Green Cynosure's most recent recommended treatment protocols. Now Cynosure recommended *at a minimum* to treat two separate areas, at 25 minutes an area, in two separate sessions—or approximately two hours of treatment time. At the other end of the spectrum, Cynosure recommended treating six separate areas (at 25 minutes each area) in three separate sessions—or over 7.5 hours of treatment time. In other words, Cynosure's initial promise that patients could undergo a one-time, 25-minute treatment and achieve a 20-24% reduction in body fat had slowly evolved into a recommendation that patients undergo a series of multiple treatments spanning several hours and involving different sessions to achieve their “desired goals.” Cynosure's new protocol revealed a lack of faith in the effectiveness of its own machine.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegation that “[i]n June 2017, Dupree emailed to Green Cynosure's most recent recommended treatment protocols” and therefore neither admits nor denies such allegations but demands strict proof thereof. Cynosure denies the remaining allegations as stated in Paragraph 86 of Plaintiff's Class Action Complaint.**

87. As Cynosure failed to deliver consistent information about the device or provide guidance as to how to remedy any of its issues, Green grew frustrated. The procedure strained her practice, both mentally and financially. It had not been the so-called “easiest laser” to operate, always requiring someone in the room with the patients to coach them through the pain. Customers

routinely complained, both of the pain and lack of results. And, unlike with other treatments, they never provided referrals following their results. Refunds or courtesy treatments were common.

**ANSWER: Cynosure denies that it failed to deliver consistent information about the device or provide guidance as to how to remedy any of its issues. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 87 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

88. In short, SculpSure failed as a viable treatment in her practice and threatened her reputation.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 88 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

89. By June 2017, The Face Place stopped actively selling the procedure. Come July, it decided to no longer sell the treatment and asked Cynosure for a refund; the request has gone unanswered.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 89 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

4. Dermacare's SculpSure goes unused after constant complaints regarding pain and poor results

90. Dermacare of Hampton Roads is a med spa in Chesapeake, Virginia, offering various cosmetic and aesthetic medical treatments to its patients.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 90 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

91. In May 2015, Dermacare received an email from Cynosure introducing SculpSure. In that email, Cynosure touted that "SculpSure™ is a clinically proven and safe treatment designed to reduce fat non-invasively by disrupting subcutaneous fat cells with a hands free treatment in just 25 minutes." The email contained a quote from CEO Michael Davin stating that SculpSure is "*highly effective in reducing adipose tissue and does so in significantly less time than other current treatments.*" Davin also claimed that "*the combination of these benefits enables us to offer practitioners the lowest total cost of ownership of any non-invasive lipolysis treatment on the market today, which in turn significantly enhances their return on investment.*"

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 91 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

92. In late-November 2015, Dermacare's owner, Leon Garber, also heard about SculpSure from a friend. So Garber reached out in early December to a sales representative for Cynosure with whom he had previously discussed other products. During that phone call, the sales representative repeated the same promises from Cynosure's marketing; namely that SculpSure: (a) was equally or more effective than its competitors in just one 25-minute treatment; (b) was "pain-free;" and (c) was so easy to use the operator could leave the room during the procedure.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 92 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

93. Based on Cynosure's these representations and Cynosure's marketing, Garber decided in mid-December to acquire a SculpSure for Dermacare.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 93 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

94. Cynosure delivered the device to Dermacare on January 12, 2016. In mid-February, a Cynosure representative visited Dermacare's offices to provide on-site training for Dermacare staff. During that training, the Cynosure representative again represented SculpSure as a one-and-done treatment. The representative further explained that Dermacare's staff member need only be present for the initial five minutes during "build mode." After that, staff members could attend to other matters, leaving the patient in the room with a buzzer to page them should the patient feel uncomfortable and need an "Advance-to-Cool" shot.

**ANSWER: Cynosure admits only that it shipped a SculpSure to Dermacare on January 7, 2016 and that initial clinical trainings on SculpSure were conducted by Cynosure at Dermacare's offices on February 20, 2016 and February 25, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 94 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

95. Following training, Dermacare staff practiced using the machine for approximately two weeks before beginning to treat patients using the recommended Zone Adjustment Chart in early March 2016. According to Cynosure, Dermacare would end up treating most patients at about 1.0 W/cm<sup>2</sup> using this method, and achieve results. But in practice, Dermacare's patients saw no results being treated at this level.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 95 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

96. Patients began complaining to Dermacare about their results with SculpSure immediately, beginning in late-April. By July 2016, Dermacare attempted to remedy the problem by offering dissatisfied patients retreatment with the device at no charge. Yet retreatment did not prove successful either.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 96 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

97. Nor could Dermacare simply turn the power level up. Many patients reported intolerable pain, especially at higher levels. In some instances, the pain prompted patients to curse, scream, or jump off the treatment table.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 97 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

98. By September 2016, Dermacare's staff could no longer trust the device and Garber recognized that his practice would suffer should he continue to perform SculpSure on his clients. Instead of experiencing a so-called "combination . . . of benefits," Garber had experienced a series of problems. And instead of experiencing the "low[] cost of ownership," Garber had been providing free retreatments and refunds, while making massive monthly payments and paying for consumable PAC Keys. Around this time, Dermacare stopped using the machine almost entirely.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 98 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

99. Despite its SculpSure now going unused, Dermacare must continue to pay \$3,712.68 monthly to lease the device. And since the device's shortcomings leave Dermacare with no ability to recoup that cost, SculpSure remains a constant drain on the finances of the company.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 99 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**5. SculpSure proves unworkable for Enhanced Image Med Spa and threatens the financial health of the business**

100. Enhanced Image Med Spa offers a variety of cosmetic, facial, and laser treatments from its offices in Glendale, Arizona. It is run by Jennessa Iannitelli, D.O.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 100 of Plaintiff's Class Action**

**Complaint and therefore neither admits not denies such allegations but demands strict proof thereof.**

101. In late-2015, Enhanced Image had been working with Sharon Knecht from Cynosure to trial Cynosure's Elite device for its practice. While working together, Knecht suggested Enhanced Image also consider purchasing SculpSure.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 101 of Plaintiff's Class Action Complaint and therefore neither admits not denies such allegations but demands strict proof thereof.**

102. Knecht introduced Dr. Iannitelli to another Cynosure sales representative, Justin Thompson. Thompson quickly forwarded Dr. Iannitelli SculpSure promotional materials and videos advertising the results achieved in a single 25-minute treatment, the absence of pain, and the "hands-free" operation.

**ANSWER: Cynosure admits only that Justin Thompson is a Cynosure representative who has provided information about the SculpSure to Enhanced Image. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 102 of Plaintiff's Class Action Complaint and therefore neither admits not denies such allegations but demands strict proof thereof.**

103. Consistent with the marketing materials, the representatives claimed that SculpSure would be pain-free and easily tolerable; the device would merely produce a warming sensation and would not require anesthetic or analgesics. Thompson and Knecht likewise stressed the impressive results SculpSure could achieve, asserting the device would eventually replace Dr. Iannitelli's liposuction practice. Thompson and Knecht repeated the claims from Cynosure's marketing

brochures: just a single 25-minute treatment would achieve visible results in the form of a 20-24% fat reduction in the treated area. Lastly, they explained SculpSure's ease of use, noting that operators simply had to initiate the procedure for a few minutes before they could leave the room and do something else around the office.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 103 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

104. Based on all of these representations about SculpSure, Dr. Iannitelli agreed to purchase a demo unit, financing the \$163,750 sales price with Ovation Finance.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 104 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

105. Following delivery of the device, on February 23, 2016, Sheena Kapukui of Cynosure visited Enhanced Image to train Dr. Iannitelli and the staff. As part of that training, Kapukui performed treatments on three of those present, where the device initially demonstrated a potential for problems. One of the staff members had difficulty tolerating the procedure because of the excess heat and pain it caused her. And none of those treated showed any results, to say nothing of the 24% reduction promised.

**ANSWER: Cynosure admits only that on February 23, 2016, Sheena Kapukui conducted an initial SculpSure training at Enhanced Image and that as part of that training, Kapukui oversaw treatments on Enhanced Image staff members. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the**

**remaining allegations contained in Paragraph 105 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

106. The problems only continued. Many of the practice's initial patients reported being miserable from the excess heat and pain, and some accused the practice of lying about SculpSure's tolerability. One patient demanded that the treatment be stopped mid-procedure and stormed out of the office.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 106 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

107. Nor did SculpSure produce results. Patients continuously failed to demonstrate any fat loss, even after multiple treatments. Indeed, some staff members had been treated up to four times, and still did not see results. Some upset patients referred to the practice as "snake oil salesmen."

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 107 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

108. In early December 2016, during a third training session with SculpSure, Dr. Iannitelli and her staff aired their frustrations to Wanda Cummings, a consultant for the company. Cummings responded that Cynosure should not have made the promises it did—namely, regarding SculpSure's efficacy, propensity for pain, and functionality—for none of them were true.

**ANSWER: Cynosure admits only that Wanda Cummings conducted a follow-up visit and SculpSure training at Enhanced Image on December 9, 2016. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 108 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

109. Ultimately, Enhanced Image had to cease performing the procedure on patients. It simply could not continue to recommend SculpSure in good faith to patients when Dr. Iannitelli and the staff did not believe the machine could produce the results the patient sought. To otherwise continue to treat patients risked harming the practice. Enhanced Image had already lost plenty of clients and good will from the many painful and unsuccessful treatments to that point. It could not afford to lose more. SculpSure now goes unused, unable to recoup the massive costs—financial and otherwise—it has cast upon the practice.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 109 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

**6. Options Medical Weight Loss refunds nearly all of its patients treated with SculpSure due to poor results**

110. Options Medical Weight Loss is a weight loss center in Chicago, Illinois. It is run by William Barton, Dr. Matt Walker, and Dr. Katrina Mattingly.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 110 of Plaintiff's Class Action**

**Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

111. In 2016, Mr. Barton began researching body contouring devices for use in the Options Medical Weight Loss center. He initially expressed interest in purchasing a CoolSculpting device and posted on Facebook seeking input. That Facebook post led him speaking to a woman who recommended that he also look at SculpSure. Barton contacted Cynosure to learn more.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 111 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

112. On September 19, 2016, Barton met with Brad Hohenstein of Cynosure. Hohenstein wasted no time detailing all of the ways that SculpSure beats CoolSculpting, mirroring the promises made in Cynosure's marketing. He noted that SculpSure achieves up to 24% fat reduction in just one 25-minute treatment. Hohenstein also remarked on the lack of pain during the procedure and the simplicity of operating the device, which allowed the operator to leave the room.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 112 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

113. Cynosure sales representatives also emailed Barton providing links to marketing materials and videos, repeating these claims. For example, one marketing brochure stated that one 25 minute procedure would "permanently destroy up to 24% of treated fat." And videos showed the operator leave the room while the patient casually received the treatment without any pain.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 113 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

114. Based on Cynosure's uniform representations, Barton, Walker, and Mattingly opted to purchase the device.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 114 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

114. Following delivery, Tina Bock from Cynosure came to Options Medical Weight Loss Center in the Fall of 2016 to train the staff. As part of the training, Bock treated any staff members who would volunteer. Once one staff member suffered from searing pain, the rest of the staff refused to volunteer.

**ANSWER: Cynosure admits only that Tina Bock conducted an initial SculpSure training at Options Medical Weight Loss Center on October 25, 2016 and that she oversaw SculpSure treatments as part of that training. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 114 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

115. Bock also advised the staff of the "Treat to Complete" protocol, where some patients with a higher body mass index may require multiple procedures to get results. This was the first anyone from Options Medical had heard of "Treat to Complete" or the need for additional

treatments; all of the marketing Options Medical had seen or heard to that point claimed the device was effective after one session.

**ANSWER: Cynosure admits only that its “Treat to Complete” treatment plan notes that multiple treatments may be part of the treatment plan for some patients. Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 115 of Plaintiff’s Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

116. Similarly, it soon became clear that the level of pain far exceeded that which Cynosure had advertised in its marketing. Some patients described it as “intense” or “excruciating.” And given the discomfort of the patients, the staff, which had been scheduled to work on other things, could not leave the room.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 116 of Plaintiff’s Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

117. The patients’ pain did not pay off with results either. Patients complained. One even filed a complaint with the FDA, claiming the device does not work. By early 2017, Barton found himself having to refund (or offer free services) to almost every patient who had received SculpSure.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 117 of Plaintiff’s Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

118. Barton has unsuccessfully attempted to work with Cynosure about the device's shortcomings and the unsatisfied customers.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 118 of Plaintiff's Class Action Complaint.**

119. Because Cynosure will not take back the machine and because he cannot keep recommending the procedure to his clients, Barton has looked to sell the machine. But to date has been unable to do that either because he cannot find anyone willing to purchase it, let alone for an amount close to what he paid for it. Instead, the device goes unused while Options Medical continues to make payments on the device.

**ANSWER: Cynosure has insufficient knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 119 of Plaintiff's Class Action Complaint and therefore neither admits nor denies such allegations but demands strict proof thereof.**

## V. CLASS ALLEGATIONS

121. Plaintiffs bring these claims pursuant to Massachusetts General Law 93A § 11 (“G.L. 93A”), and Rules 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure. They file this action on behalf of themselves and a Nationwide Class defined as follows:

All individuals and entities in the United States who purchased or leased a SculpSure Non-Invasive Body Contouring Platform.

The definition of the Class is unambiguous. Plaintiffs are members of the Class that they seek to represent.

**ANSWER: Cynosure admits only that Plaintiffs purport to bring this action as a class action but denies that a class action is warranted and denies the remaining allegations contained in Paragraph 121 of Plaintiffs' Class Action Complaint.**

122. Under Rule 23, an action may be maintained as a class action if: (1) “the class is so numerous that joinder of all members is impracticable;” (2) “there are questions of law or fact common to the class;” (3) “the claims or defenses of the representative parties are typical of the claims or defenses of the class;” and (4) “the representative parties will fairly and adequately protect the interests of the class.”<sup>39</sup> Plaintiffs’ action meets each of these requirements.

**ANSWER: Cynosure denies that Plaintiffs’ action meets each of the requirements for class certification set forth in Fed. R. Civ. P. 23. In addition, Fed. R. Civ. P. 23 speaks for itself; to the extent the allegations contained in Paragraph 122 of Plaintiffs’ Class Action Complaint mischaracterize or misrepresent the law, Cynosure denies the same.**

**A. Plaintiffs bring their claims on behalf of numerous others**

123. The exact number of Class members is unknown and not available to Plaintiffs. But since receiving FDA 501(k) clearance in the third quarter of 2015, Defendant has sold SculpSure nationwide to hundreds of Class members, making joinder of each individual member impracticable. Ultimately, Class members can be identified through Defendant’s records.

**ANSWER: Cynosure admits only that it has sold SculpSure machines to over 200 individuals or entities. Cynosure denies the remaining allegations as stated in Paragraph 123 of Plaintiffs’ Class Action Complaint.**

**B. Plaintiffs and the Class are similarly situated and have suffered similar injuries**

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<sup>39</sup> Fed. R. Civ. P. 23(a)(1)-(4).

124. Common questions of law and fact predominate over the questions affecting only individual Class members. Some of the common legal and factual questions include:

- a. Did Cynosure promote the treatment as “painless,” “tolerable,” “comfortable,” or similarly, despite the fact that it caused great discomfort or serious pain to many patients?
- b. Did Cynosure misrepresent the effectiveness of the procedure to prospective purchasers?
- c. Did Cynosure market the treatment as “one-and-done,” “one-time,” or in a similar manner, despite questionable efficacy even after multiple treatments?
- d. Did Cynosure promise purchasers that their staff members could leave the room during the procedure, when in fact the SculpSure operator would need to remain in the room to monitor the patient throughout the procedure?
- e. Did Cynosure’s representations to the Class accurately reflect its own knowledge and research?

**ANSWER: Cynosure denies the allegations as stated in Paragraph 124 of Plaintiffs’ Class Action Complaint.**

125. All of the claims asserted by Plaintiffs are common to and typical of the Class. Plaintiffs and the Class all complain of the same product, SculpSure, and the same wrongful conduct by Cynosure in marketing that product. The misrepresentations that Cynosure made to Plaintiffs and the Class have been uniform, namely that SculpSure: (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) can be performed “hands free” without a physician and/or trained staff member present during the entire procedure.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 125 of Plaintiffs' Class Action Complaint.**

126. Likewise. Plaintiffs and the Class have suffered similar damages. Plaintiffs and the Class did not receive the benefit of the bargain and lost money in the amount spent purchasing or leasing SculpSure, buying consumable PAC Keys, and retreating patients.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 126 of Plaintiffs' Class Action Complaint.**

127. The class action device is thus superior to other available means for the fair and efficient adjudication of the claims of Plaintiffs and the Class members. The relief sought per individual member of the Class is small compared to the burden and expense that would accompany the individual prosecution of every Class member. Furthermore, it would be difficult, if not impossible, for the Class members to seek redress on an individual basis. Even if the Class members themselves could afford such individual litigation, the court system could not.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 127 of Plaintiffs' Class Action Complaint.**

128. Individual litigation of the legal and factual issues raised by the conduct of Defendant would increase delay and expense to all parties and to the court system. The Class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale, and comprehensive supervision by a single court. Given the similar nature of the Class members' claims and the application of a singular state law (due to Defendant's choice of law provision selecting Massachusetts), the Court and the parties can easily manage a nationwide Class.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 128 of Plaintiffs' Class Action Complaint.**

**C. Plaintiffs and the Class will be adequately represented**

129. Plaintiffs will fairly and adequately represent and protect the interests of the Class, and has [sic] retained counsel competent and experienced in complex litigation, including class actions. Plaintiffs have no interest antagonistic to those of the Class, and Defendant has no defenses unique to the Plaintiffs.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 129 of Plaintiffs' Class Action Complaint.**

**VI. CLAIMS ALLEGED**

**COUNT I  
VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT  
(G.L. CHAPTER 93A)**

130. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein.

**ANSWER: Cynosure incorporates by references its answers to paragraphs 1 through 129 as though fully set forth herein.**

131. This cause of action is brought by Plaintiffs pursuant to the Massachusetts Consumer Protection Act, G.L. Chapter 93A §§ 2, 11 *et. seq.*, on behalf of the Class. Section 2 of the Massachusetts Consumer Protection Act provides that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

**ANSWER: Cynosure admits only that Plaintiffs purport to bring this action pursuant to the Massachusetts Consumer Protection Act, G.L. Chapter 93A §§ 2, 11 *et.***

**seq, on behalf of the Class. The Massachusetts Consumer Protection Act speaks for itself. To the extent the allegations contained in Paragraph 131 of Plaintiffs' Class Action Complaint mischaracterize or misrepresent the law, Cynosure denies the same. Cynosure denies that Plaintiffs may properly bring this action pursuant to the Massachusetts Consumer Protection Act and denies that Plaintiffs may act on behalf of any class. Cynosure denies any remaining allegations contained in Paragraph 131 of Plaintiffs' Class Action Complaint.**

132. Plaintiffs, Class Members, and Defendant are “persons” under the Massachusetts Consumer Protection Act pursuant to G.L. Chapter 93A § 1(a).

**ANSWER: Cynosure states that the allegations of Paragraph 132 of Plaintiffs' Complaint are legal conclusions to which no answer is required. To the extent that Paragraph 132 of Plaintiffs' Complaint is deemed to contain allegations of fact and to the extent that Paragraph 68 contains misrepresentations of the law, Cynosure denies the same.**

133. SculpSure is tangible property involved in “trade” and “commerce” subject to the Massachusetts Consumer Protection Act pursuant to G.L. Chapter 93A § 1(b).

**ANSWER: Cynosure states that the allegations of Paragraph 133 of Plaintiffs' Complaint are legal conclusions to which no answer is required. To the extent that Paragraph 133 of Plaintiffs' Complaint is deemed to contain allegations of fact and to the extent that Paragraph 133 contains misrepresentations of the law, Cynosure denies the same.**

134. At all relevant times, Defendant violated and continues to violate the Massachusetts Consumer Protection Act in its transactions regarding SculpSure. Specifically,

Defendant deceives buyers by misrepresenting certain qualities and attributes of the SculpSure procedure. Defendant uniformly misrepresented to potential buyers that:

- (a) SculpSure requires only one 25-minute treatment to achieve 24% fat loss, when in fact it requires multiple treatments and still is likely to be ineffective;
- (b) the treatment was virtually painless and easily tolerable without any pain medication or anesthesia, when in fact it is very painful and patients routinely could not tolerate the procedure; and
- (c) SculpSure could be performed “hands free” without a physician or trained staff member present during the entire procedure, when in fact one was required at all times to monitor energy levels.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 134 of Plaintiffs' Class Action Complaint**

135. Defendant's deception has caused substantial injury to Plaintiffs and the Class. Plaintiffs and the Class cannot recommend a procedure that involves several painful treatments and still does not yield any meaningful result in the patient. And so they have spent hundreds of thousands of dollars on a machine that is ultimately inappropriate for their practice and does not work in a commercially viable way. The machine effectively goes unused, not only denying Plaintiffs and the Class the ability to make a profit, but also the opportunity to recoup the sizeable costs already incurred. Plaintiffs and the Class have lost money and had their businesses placed under considerable financial strain.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 135 of Plaintiffs' Class Action Complaint.**

136. Accordingly, as a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys' fees and costs.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 136 of**

**Plaintiffs' Class Action Complaint**

**COUNT II  
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

137. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein. Under Massachusetts law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind."<sup>40</sup> To be merchantable, goods must at least be "fit for the ordinary purposes for which such goods are used."<sup>41</sup>

**ANSWER: Cynosure incorporates by references its answers to paragraphs 1 through 129 as though fully set forth herein. Cynosure states that the remaining allegations of Paragraph 137 of Plaintiffs' Complaint are legal conclusions to which no answer is required. To the extent that the remaining allegations of Paragraph 137 of Plaintiffs' Complaint are deemed to contain allegations of fact and to the extent that Paragraph 137 contains misrepresentations of the law, Cynosure denies the same.**

138. Defendant is a merchant under Massachusetts law who specializes in the marketing and sale of medical devices utilizing laser technology for cosmetic and aesthetic use. Defendant designed, manufactured, and marketed SculpSure, a noninvasive body-contouring device from its offices in Massachusetts.

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<sup>40</sup> Mass. Gen. Laws Ann. ch. 106, § 2-314(1).

<sup>41</sup> Mass. Gen. Laws Ann. ch. 106, § 2-314(2)(b).

**ANSWER: Cynosure states that the allegations of Paragraph 138 of Plaintiffs' Complaint are legal conclusions to which no answer is required. To the extent that Paragraph 138 of Plaintiffs' Complaint is deemed to contain allegations of fact and to the extent that Paragraph 138 contains misrepresentations of the law, Cynosure denies the same.**

139. Beginning in late 2015, Defendant marketed and sold the SculpSure device all over the country. In selling the device, Defendant specifically targeted cosmetic and aesthetic medical practices, including small medical offices and med spas. In selling to those customers, Defendant represented that SculpSure would be appropriate for their practices, namely because it: (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) could be performed "hands free" without a physician and/or trained staff member present during the entire procedure.

**ANSWER: Cynosure admits that it began marketing and selling the SculpSure device in late 2015, and that its customers included cosmetic and aesthetic medical practices, including small medical offices and med spas. Cynosure denies the remaining allegations as stated in Paragraph 139 of Plaintiffs' Class Action Complaint.**

140. At no time, however, has SculpSure actually been suitable for the ordinary purposes for which it is intended. Even when Plaintiffs and the Class use the machine as envisioned by Defendant's marketing and as directed by Defendant, SculpSure cannot successfully be performed as a one-time treatment, frequently causes significant pain in the patient, and requires hands-on assistance from a physician or trained staff member to administer the treatment. It is thus not fit for use in medical spas, physician offices, or as otherwise marketed by Defendant.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 140 of Plaintiffs' Class Action Complaint.**

141. As a consequence, Plaintiffs and the Class have spent hundreds of thousands of dollars on a machine that is not suitable for their practices. Plaintiff [sic] and the Class have lost money and had their businesses placed under considerable financial strain. Accordingly, Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys' fees and costs.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 141 of Plaintiffs' Class Action Complaint.**

**COUNT III  
UNJUST ENRICHMENT**

142. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein.

**ANSWER: Cynosure incorporates by references its answers to paragraphs 1 through 129 as though fully set forth herein.**

143. From late 2015 to the present, Plaintiffs and the Class have purchased hundreds of SculpSure machines from Defendants [sic]. In turn, Defendant has received millions of dollars in revenue from Plaintiffs and the Class via purchases of the machine, lease agreements, and the sale of PAC Keys.

**ANSWER: Cynosure admits only that it has sold more than 200 SculpSure machines from late 2015 to the present, and that its combined gross revenue from SculpSure purchases, SculpSure lease agreements, and SculpSure PAC key sales exceeds \$2 million.**

144. Defendant has frequently touted the success of its sales of SculpSure, directly attributing the company's record revenues to sales of the machine.<sup>42</sup> Likewise, Hologic, Inc., who acquired Defendant for approximately \$1.44 billion in early 2017, consistently singled out SculpSure when discussing reasons for the massive acquisition of the company.<sup>43</sup>

**ANSWER: Cynosure denies the allegations as stated in Paragraph 144 of Plaintiffs' Class Action Complaint.**

145. Defendant's enormous financial gains, however, come at the expense of the financial distress placed upon Plaintiffs and the Class. Plaintiffs and the Class purchased SculpSure because Defendant marketed the device as not only suitable for their practice, but as premier technology. Specifically, Defendant touted certain attributes, namely that SculpSure (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) could be performed "hands free" without a physician and/or trained staff member present during the entire procedure.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 145 of Plaintiffs' Class Action Complaint.**

146. But in practice, SculpSure has shown to possess none of these characteristics. The procedure cannot successfully achieve results as a one-time treatment. SculpSure causes significant pain in countless patients. And requires hands-on assistance from a physician or trained staff member to administer the treatment. Because Plaintiffs and the Class cannot recommend a procedure that involves several painful treatments and does not yield any meaningful results, the machines effectively go unused.

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<sup>42</sup> CYNO — Q2 2016 Cynosure Inc Earnings Call, at 3 (Jul. 26. 2016).

<sup>43</sup> HOLX — Hologic Inc to Acquire Cynosure Inc Conference Call. at 4. 6-7. 9 (2017)

**ANSWER: Cynosure denies the allegations as stated in Paragraph 146 of Plaintiffs' Class Action Complaint.**

147. Accordingly, it would be inequitable and unjust for Defendant to retain its ill-gotten fortune. Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys' fees and costs.

**ANSWER: Cynosure denies the allegations as stated in Paragraph 147 of Plaintiffs' Class Action Complaint.**

**WHEREFORE, Defendant, CYNOSURE, INC., respectfully requests that judgment be entered in its favor and against Plaintiffs with costs assessed against Plaintiffs.**

**JURY DEMAND**

Defendant demands a trial by jury for all issues so triable.

**AFFIRMATIVE DEFENSES**

**NOW COMES** the Defendant, CYNOSURE, INC., by and through its attorneys, SMITHAMUNDSEN LLC, and for its Affirmative Defenses to Plaintiffs' Class Action Complaint, states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims and requests for relief are barred, in whole or in part, because any alleged damages and/or injuries are due to and caused by the actions and/or omissions of Plaintiffs, which actions and/or omissions are the proximate cause of the alleged damages and/or injuries.

**SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims and requests for relief are barred, in whole or in part, because Plaintiffs

failed to mitigate their damages.

**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' claims and requests for relief are barred, in whole or in part, by waiver.

**FOURTH AFFIRMATIVE DEFENSE**

Cynosure hereby gives notice that it intends to rely upon such other and further affirmative defenses and counterclaims as may become available or apparent and hereby reserves its right to amend its Answer and Affirmative Defenses to assert such defenses or claims.

Respectfully submitted,

October 31, 2017

By: /s/ Yesha Hoeppner  
Counsel for Defendant, CYNOSURE, INC.

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**CERTIFICATE OF SERVICE**

I, Yesha Hoeppner, hereby certify that on the 31<sup>st</sup> day of October, 2017, the foregoing document, filed through the CM/ECF System, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

/s/ Yesha Hoeppner